

EVALUATION GUIDANCE TO THE PEER REVIEW PANEL FOR THE REVISED UP AND DOWN PROCEDURE (UDP)

Review of the Revised Draft UDP Test Guideline, a Procedure for Calculating Confidence Intervals for the LD50, and a Software Program for use with the UDP

Instructions for the Peer Review Panel

The Panel is asked to review: 1) the revised draft UDP; 2) the proposed procedure for calculating the confidence interval for the LD50; and 3) the UDP software program. In reviewing these documents/products, the Panel is asked to consider all of the information provided and develop written responses to the questions below. The Panel is asked to prepare a written report summarizing their review.

This review will focus on the following:

1. The revised draft UDP test guideline (June 20, 2001) incorporates modifications in accordance with the Panel's recommendations at the July 25, 2000 Peer Review Panel meeting.
 - a) Are the changes consistent with the Panel's recommendations?
 - b) Do you concur with the revisions that have been made?

Note: This revised draft UDP test guideline (GUIDELINE FOR THE TESTING OF CHEMICALS: Acute Oral Toxicity: Revised Up-and-Down Procedure. Draft, July 12, 2001) was developed by UDP Technical Task Force and submitted to ICCVAM on July 12, 2001. To allow comparison with the version reviewed by the Panel (Revised Test Guideline 425N, April 11, 2000), a Summary of Changes document is being distributed to the Panel.

2. Is the proposed procedure for calculating a confidence interval for the LD50 appropriate and adequate for use with the revised draft UDP test guideline?

Note: This document, "Description of Performance and Confidence Intervals for the Revised Up-and-Down Procedure (UDP) for Acute Oral Toxicity. June 6, 2001," was developed by the U.S. EPA and submitted to ICCVAM for distribution to the Panel members.

3. Is the software program adequate and consistent with the procedures in the revised draft UDP test guideline?

Note: This software program and accompanying user's manual (Acute Oral Toxicity (Guideline 425) Statistical Program. May 2001) were developed by Westat, Inc. for the U.S. EPA and submitted to ICCVAM for distribution to the Panel members.

